

Message

From: McClure, Peter [mcclure@srcinc.com]
Sent: 6/6/2014 3:29:49 PM
To: Pratt, Margaret [pratt.margaret@epa.gov]; Chiu, Weihsueh [Chiu.Weihsueh@epa.gov]; Hogan, Karen [Hogan.Karen@epa.gov]; Rice, Glenn [rice.glenn@epa.gov]
CC: Carlson-Lynch, Heather [hclynch@srcinc.com]; Melia, Julie [jmelia@srcinc.com]
Subject: PAH RPF IRIS project: More comments and questions on analysis of "Zero-Incidence" data sets

Margaret —

Thanks for sending Karen's additional instructions. From them, it appears that we made three erroneous assumptions:

Ex. 5 Deliberative Process (DP)

If a study has or will have a calculated RPF (based on BMDs), should that value be used in place of the cRPF?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Peter

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From: Pratt, Margaret [mailto:pratt.margaret@epa.gov]
Sent: Tuesday, June 03, 2014 6:26 PM
To: McClure, Peter; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn
Cc: Carlson-Lynch, Heather; Melia, Julie
Subject: RE: PAH RPF IRIS project: Analysis of "Zero-Incidence" data sets

Hi Peter,

Karen hasn't had an opportunity to thoroughly look over the email you sent earlier today, but she did bring to my attention the fact that I neglected to forward some of the information that was supposed to go to SRC. I apologize for the confusion.

The following are examples and discussion that should also have been sent to you with what you received previously (below). I've highlighted where SRC's response today differed from Karen's examples in the previously omitted information:

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Please let me know if you have questions or comments about any of this.

Thanks!
Margaret

Once again, my apologies for the confusion. I look forward to receiving your comments.

Margaret

From: McClure, Peter [<mailto:mcclure@srcinc.com>]
Sent: Tuesday, June 03, 2014 2:53 PM
To: Pratt, Margaret; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn
Cc: Carlson-Lynch, Heather; Melia, Julie
Subject: PAH RPF IRIS project: Analysis of "Zero-Incidence" data sets

Margaret –

We have applied the methodology outlined in your email to determine which studies will be considered to be null (i.e., not useful for RPF derivation), based on inadequate dose level to elicit a response. In applying the methodology, we made certain assumptions as outlined below.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Please let us know if these thoughts and results are in line with your technical directive.

Thank you,
Peter

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From: Pratt, Margaret [<mailto:pratt.margaret@epa.gov>]
Sent: Monday, June 02, 2014 9:52 AM
To: McClure, Peter; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn
Cc: Carlson-Lynch, Heather; Melia, Julie
Subject: RE: Call notes May 27 and revised RPF status spreadsheet

Hi Peter,

Thanks for the notes. After an initial look, I saw nothing that needed to be changed. I will let you know if someone else did.

Ex. 5 Deliberative Process (DP)

Please let me know if you have questions or comments about any of this.

Thanks!
Margaret

PS – Apologies for the delay response. Was on sick leave late last week.

From: McClure, Peter [<mailto:mcclure@srcinc.com>]
Sent: Wednesday, May 28, 2014 11:57 AM
To: Pratt, Margaret; Chiu, Weihsueh; Hogan, Karen; Rice, Glenn
Cc: Carlson-Lynch, Heather; Melia, Julie
Subject: Call notes May 27 and revised RPF status spreadsheet

Margaret et al.

Attached are notes for the May 27 call and a revised tracking spreadsheet in accordance with our discussions yesterday. The revised spreadsheet identifies additional “time-course” data sets that will need Bayesian analysis. We look forward to receiving information on blue and orange highlighted studies in the current version.

Let us know if you have questions or comments.

Thank you,
Peter

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